K120877

JUN 20 2012

5. 510(k) SUMMARY AS REQUIRED BY SECTION 807.92(C)

Submitted by: Mrs. Mitsuko Yoneyama
President

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Date Submitted: March 19, 2012

Device Identification:

Trade Name:	NAI-5 Micromanipulator Set
Common Name:	Micromanipulator Set
Classification Name:	Assisted Reproduction Micromanipulators and Microinjectors (21 CFR, 884.6150)

Predicate Device:

Narishige Co., Ltd. claims the NAI-5 Micromanipulator Set as substantially equivalent to a system that has combined two predicate devices: MM-89 Motor-drive Manipulator (Premarket Notification 510(k) Number: K002291) and MMO-202ND Three-axis Hanging Joystick Oil Hydraulic Micromanipulator (Premarket Notification 510(k) Number: K002659).

Device Description:

The NAI-5 Micromanipulator Set enables coarse and fine positioning of a microtool under the microscope and is used in assisted reproduction procedures.
The NAI-5 Micromanipulator Set consists of motor-driven coarse manipulators that enable coarse movement operation and oil hydraulic micromanipulators that enable fine movement operation.

Intended Use:

The NAI-5 Micromanipulator Set enables coarse and fine positioning of a microtool under the microscope and is used in assisted reproduction procedures.

Technological Characteristics:

The NAI-5 Micromanipulator Set consists of motor-driven coarse manipulators that enable coarse movement operation and oil hydraulic micromanipulators that enable fine movement operation.

The specifications of the NAI-5 are summarized in the comparison table below.

Comparison Table

	NAI-5 **Micromanipulator Set**	MM-89 Motor-drive Manipulator	MMO-202ND Three-axis Hanging Joystick Oil Hydraulic Micromanipulator
510(k) Status and number	Subject Device	Predicate Device	Predicate Device
		K002291	K002659
Type of manipulator	Coarse and fine	Coarse only	Fine only
Type of control	Motorized and Oil Hydraulic control	Motorized control	Oil Hydraulic control
Configuration	Coarse and Fine Drive Units, Coarse and Fine Control Units, and Power Supply	Coarse Drive Unit, Coarse Control Unit, and Power Supply	Fine Drive Unit, and Fine Control Unit
Identification of each axis	X-axis, Y-axis, and Z-axis (coarse and fine)	X-axis, Y-axis, and Z-axis (coarse only)	X-axis, Y-axis, and Z-axis (fine only)

(The table is continued to the next page.)

	(NAI-5)	(MM-89)	(MMO-202ND)
Movement Range of each axis	Coarse: 22mm Fine: 10mm	Coarse: 22mm	Fine: 10mm
Dimensions of Drive Unit	W57 x D138 x H94mm (Coarse and fine combined)	W80 x D116 X H142mm	W40 x D46 x H87mm
Dimensions of Motorized Control Unit	W70 x D100 x H120mm		N/A
Dimensions of Hydraulic Control Unit	W65 × D180 × H175mm	N/A	W165 x D80 x H175mm
Dimensions of Power Supply	W125 x D105 x H85mm		N/A
Intended Use	The **NAI-5** Micromanipulator Set enables coarse and fine positioning of a microtool under the microscope and is used in assisted reproduction procedures.	The MM-89 Motor-drive Manipulator helps coarse positioning of a microtool under the microscope and is used in assisted reproduction procedures.	The MMO-202ND Three-axis Hanging Joystick Oil Hydraulic Micromanipulator helps fine positioning of a microtool under the microscope and is used in assisted reproduction procedures.

Substantial Equivalence:

Narishige Co., Ltd. claims the NAI-5 Micromanipulator Set as substantially equivalent to a system that has combined two predicate devices: MM-89 Motor-drive Manipulator (Premarket Notification 510(k) Number: K002291) and MMO-202ND Three-axis Hanging Joystick Oil Hydraulic Micromanipulator (Premarket Notification 510(k) Number: K002659).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Mrs. Mitsuko Yoneyama
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TOKYO 157-0062
JAPAN

Re: K120877
Trade/Device Name: NAI-5 Micromanipulator Set
Regulation Number: 21 CFR§ 884.6150
Regulation Name: Assisted reproduction micromanipulators and microinjectors
Regulatory Class: II
Product Code: MQJ
Dated: March 23, 2012
Received: March 23, 2012

Dear Mrs. Yoneyama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use:

510(k) Number (if known): K120877

Device Name: NAI-5 Micromanipulator Set

Indications for Use: The NAI-5 Micromanipulator Set is used for coarse and fine positioning of a microtool under the microscope and is used in assisted reproduction procedures.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120877